

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

FILED
Jan 11, 2025, 9:47 PM
in the Clerk's Office
U.S. District Court,
EDNY, Brooklyn
Pro Se Office via
Box.com

UNITED STATE OF AMERICA
PLAINTIFF

§

v.

Case No. 22-CV-1159
January 11, 2025.

§

ANDREW SINCLAIR / B4B EARTH TEA
LLC
DEFENDANT

RESPONSE TO REBUTTAL EXPERT REPORTS

This response addresses rebuttal reports by Dr. James P. McCormac and Dr. Mariton Daniel dos Santos, clarifying and defending the scientific evidence supporting B4B Earth Tea Immune Support Drink, its regulatory compliance, and its proper classification as a dietary supplement.

Plaintiff's allegations are based on conjecture and mischaracterizations, lacking factual support. By contrast, Defendant provides robust scientific validation and real-world evidence, fully substantiating the product's immune support claims.

I. INTRODUCTION

The Plaintiff accuses the Defendant of fraud, false advertising, and making unsubstantiated health claims about B4B Earth Tea immune support drink. These accusations, however, lack merit and are unsupported by independent scientific evidence or direct experience with the product.

The Defendant has provided credible scientific studies, including the ELISA COVID-19 Spike ACE2 study, which demonstrates 99% inhibition of spike protein

binding and directly addresses the concerns raised by Dr. McCormac in paragraph 3 of his rebuttal, which challenges the relevance of in vitro studies. The Defendant has attached the following exhibits:

1. Exhibit 1: IMMUNE STUDY (the lab report)
2. Exhibit 2: ELISA Immune Study Raw Data (supporting lab documents)
3. Exhibit 3: Immune Study Manual (supporting lab documents)

Together, these exhibits establish B4B Earth Tea's immune-supportive properties and its measurable effects on key cytokines involved in immune regulation.

These findings, combined with real-world user feedback, validate the product's ability to support immune function.

1. RESPONSE TO DR. MARITON DANIEL DOS SANTOS

Mischaracterization of B4B Earth Tea's Claims

Dr. dos Santos alleges that the Defendant's marketing misrepresents B4B Earth Tea as a cure or treatment for COVID-19 and other illnesses. This assertion is categorically false. The Defendant has consistently marketed the product as a dietary supplement designed to support immune function, not as a cure or treatment for any illness. Under DSHEA guidelines, dietary supplements are permitted to make structure/function claims, such as "supports immune health," which are distinct from drug claims. All labeling refers to the product in question as a 100% natural immune support drink.

Statements from users and shared submitted feedback reflect personal experiences and reported benefits, not official marketing claims. Success stories emphasize the role of a healthy immune system in preventing and recovering from illness, which aligns with established scientific understanding:

The Defendant draws support from the National Institutes of Health (NIH) article, "The Effect on the Immune System in the Human Body Due to COVID-19: An Insight on Traditional to Modern Approach as a Preventive Measure":

“The immune system protects against many infectious diseases including COVID-19. The human body’s immune system can defend against various types of diseases, maintain physical condition, protect against harmful effects of substances, and fight germs. The innate immunity is a protection mechanism (primary line), which is related to the host immune system. The innate immune system’s impacts can theoretically play an important role to prevent COVID-19 viral disease.”
(Source: <https://pmc.ncbi.nlm.nih.gov/articles/PMC8716700/>)

Additionally, the Plaintiff’s assertion that clinical trials are required to substantiate the Defendant’s claims demonstrates a misunderstanding of DSHEA requirements. Clinical trials are not a formal requirement for structure/function claims for dietary supplements. Under DSHEA, dietary supplement manufacturers can make these claims without FDA pre-approval, provided they have competent and reliable scientific evidence to support them. This evidence can include a range of scientific research, such as animal studies, human observational studies, in vitro studies, or literature reviews, and does not necessitate clinical trials. The FDA mandates that manufacturers substantiate their claims but does not require clinical trials specifically for this purpose
(Source: <https://www.naturalproductsinsider.com/claims/clinical-trials-putting-proof-back-health-claims>).

The Plaintiff’s failure to differentiate between structure/function claims, which are legal under U.S. law, demonstrates a fundamental misunderstanding of the regulatory guidelines governing dietary supplements and the role of the immune system in health.

The Defendant’s confident and transparent posts about B4B Earth Tea immune support drink seem to have upset the Plaintiff, who cited numerous confident posts by the Defendant as grounds to label B4B Earth Tea immune support drink a drug.

2. RESPONSE TO REBUTTAL EXPERT REPORT OF DR. JAMES P. McCORMAC

In paragraph 3 of his rebuttal, Dr. McCormac asserts that “in vitro studies do not replicate or demonstrate what would go on with a compound when it is put inside a human body, which has an immune system.” This statement misrepresents the purpose of in vitro studies and overlooks complementary evidence supporting B4B

Earth Tea immune support drink's efficacy.

- **Complementary Evidence:**

To counter the Plaintiff's assertions, I, the Defendant, submit an ELISA immune cytokine study as Exhibit IMMUNE STUDY. This study provides compelling evidence of the product's efficacy after entering the body, where the immune system and natural biological mechanisms take control.

- **Unique Mechanism of Action:**

Unlike pharmaceutical drugs, which rely on active ingredients to deliver synthetic compounds, B4B Earth Tea immune support drink contains natural plant-based compounds that are bioavailable and understood by the body. The immune cytokine study, conducted using RayBiotech's human biology protocols, demonstrates the product's effectiveness in modulating key cytokines like IL-6 and TNF- α , crucial for immune regulation and inflammation control.

Additionally, the RayBiotech COVID-19 Spike ACE2 study was conducted with both negative and positive controls to ensure the accuracy and reliability of its findings. This strengthens the validity of the results and the evidence supporting B4B Earth Tea's immune-supportive properties.

The Plaintiff's assertion that B4B Earth Tea immune support drink is ineffective is refuted by this combination of scientific and real-world evidence.

2a. Immune Cytokine Study Findings

The immune cytokine study demonstrates B4B Earth Tea's measurable impact on cytokines associated with immune function and inflammation, particularly those linked to COVID-19. The Quantibody® Human Inflammation Array 1 study by RayBiotech focused on key cytokines such as IL-1 α , IL-1 β , IL-6, IL-8, TNF- α , and IFN- γ , critical to regulating immune responses.

- Results show significant modulation of cytokine levels, indicating B4B Earth Tea's potential to balance immune responses.

- For instance, IL-6 and TNF- α , key markers of inflammation in severe COVID-19 cases, showed moderated levels in treated samples, suggesting reduced overactive inflammatory responses.

These findings align with the product's intended role as an immune support supplement and substantiate marketing claims within DSHEA guidelines.

2b. Relevance to COVID-19 and Inflammatory Responses

The study also highlights cytokine regulation's importance in infections such as COVID-19:

This evidence also aligns with the conclusions of the NIH article, "Cytokine Storms in Severe COVID-19 Cases":

"Cytokine storms, characterized by the overproduction of pro-inflammatory cytokines, are a hallmark of severe COVID-19, contributing to disease progression and severity. Regulation of cytokines like IL-6 and TNF- α can mitigate inflammatory responses and support immune balance."

(Source: <https://pmc.ncbi.nlm.nih.gov/articles/PMC9064717/>)

By demonstrating cytokine modulation, the ELISA immune cytokine study provides robust evidence of the product's efficacy in supporting immune function, further substantiating its structure/function claims under DSHEA guidelines.

2c. Support for Broader Feedback on Cytokine-Related Health Issues

In addition to scientific studies, I have relied on direct feedback from users, including reviews, personal experiences, and conversations with volunteers. Unlike other manufacturers who base marketing solely on historical ingredient benefits, B4B Earth Tea emphasizes hundreds of real-world results and user insights.

The immune cytokine study provides scientific validation for feedback received about the product's effects. It demonstrates that B4B Earth Tea has the potential to modulate key cytokines like IL-6 and TNF- α , supporting immune function and addressing conditions like chronic inflammation and fatigue.

This study provides a scientifically valid foundation for understanding the product's biological activity. Furthermore, the results were obtained despite dilution and filtration, emphasizing the robustness of B4B Earth Tea immune support drink's natural compounds.

3. Preliminary Clinical Data

A small-scale exploratory trial conducted in India provides additional evidence of B4B Earth Tea's immune-supportive benefits. The trial included 15 participants, all of whom experienced significant recovery within a short period of using the product. While the trial's scope was limited due to budgetary constraints, the 100% recovery rate demonstrates the product's potential effectiveness and highlights the need for further large-scale clinical studies to validate these findings.

4. VALIDATION OF THE ELISA STUDY

The ELISA COVID-19 Spike ACE2 study, conducted by the ISO 13485:2016-certified RayBiotech laboratory, provides compelling evidence of B4B Earth Tea's efficacy. Key findings include:

- Unfiltered Samples (99% v/v): Inhibition rates of 98.398% at 4°C and 98.750% at room temperature.
- Filtered Samples (99% v/v): Inhibition rates of 74.536% at 4°C and 83.930% at room temperature.

These results validate the biological activity of the product, even after laboratory-induced dilution and filtration. The high inhibition rates observed in unfiltered samples reflect the drink's robust natural compounds, further underscoring its effectiveness as an immune support supplement.

As noted in the affidavit submitted with the study, the product directions specify that B4B Earth Tea immune support drink is to be consumed as is—hot or cold—without any need for dilution or filtration. This context highlights that the laboratory's induced filtering and diluting processes were purely experimental and not representative of typical consumer use, emphasizing the product's potency when used as intended.

These findings reinforce the product's structure/function claims under DSHEA guidelines and provide credible evidence of its immune-supportive properties.

5. AUTHOR AND STUDY CREDIBILITY

The Plaintiff's critique of the author's role does not diminish the validity of the study. The results of the Spike-ACE2 study are self-explanatory and were conducted by RayBiotech, a trusted laboratory certified under ISO 13485:2016 and cGMP standards.

The author of the report, hired as a freelance professional, independently interpreted the data provided by RayBiotech without any association with the Defendant. The findings and conclusions are based solely on the scientific evidence presented by the study, further emphasizing the objectivity and credibility of the results.

6. DOCTORS DO NOT DEVELOP PRODUCTS

While doctors can provide valuable input during clinical trials or after a product reaches patients, the actual development of products, particularly natural supplements, is not typically within the scope of their expertise. The rebuttal reports reveal that both experts lack familiarity with the structure/function claims policy and are not experts in product development.

The reports also indicate conflict of interest and bias in their findings. Their questions regarding how natural product compounds are delivered expose a lack of experience with herbal and alternative remedies. Doctors unfamiliar with plant-based therapies often demand isolated active ingredient details because they do not view nature and the human body as interrelated systems. This highlights a fundamental gap in understanding natural products like B4B Earth Tea immune support drink, which rely on the synergistic effects of whole plant compounds rather than isolated synthetic ingredients.

Furthermore, the repeated insistence on clinical trials demonstrates that the experts are paid to promote the Plaintiff's narrative that B4B Earth Tea immune support drink should be classified as a drug. This approach ignores existing legal frameworks such as the Dietary Supplement Health and Education Act (DSHEA), which regulates natural products and allows structure/function claims such as "supports immune health" without requiring clinical trials.

Neither of the rebuttal experts has developed a product, nor do they demonstrate the expertise necessary to evaluate the unique properties of herbal and plant-based remedies. Their opinions reflect a clear bias against natural products and disregard the legal standards that govern dietary supplements.

7. CONCLUSION

The Defendant has provided extensive scientific evidence, including the ELISA and immune cytokine studies, to substantiate the immune-supportive properties of B4B Earth Tea. The Plaintiff's allegations are unsupported by scientific data and rely on mischaracterizations and opinions rather than facts.

The Defendant respectfully requests that the Court recognize the following:

1. B4B Earth Tea's compliance with DSHEA guidelines.
2. The scientific validity of the ELISA and immune cytokine studies.
3. The Plaintiff's failure to produce independent evidence contradicting the Defendant's claims.

Immune support is a foundational element of health, and the Defendant's marketing reflects this reality without overstepping regulatory boundaries. The allegations brought forth by the Plaintiff are unsubstantiated and should be dismissed.

Respectfully submitted,

/s/ Andrew Sinclair

Andrew Sinclair

Defendant

9703 Sutphin Blvd

unit 350008

Jamaica NY 11435

718-635-2135

Asinclairhg@gmail.com